K031503

510(K) SUMMARY

OCT 2 4 2003

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: AViTA Corp
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Contact: Mr. Geo Lin, General Manager

2.0 Device Name: **AViTA TS8/TS9 Series IR Ear/ Forehead Thermometer**
Model no.:
TS-802 3 in 1 Ear/ Forehead/Room Thermometer for the TS8 Series ,
TS-902 2 in 1 Ear/ Forehead Thermometer for the TS9 Series.

3.0 Classification: Class II

4.0 Predicate Device: **AViTA TS8/TS9 IR Ear/ Forehead Thermometer** has similar general design with

- **AViTA TS2(Piccolo)/TS4(Exato) Infrared Ear Thermometer (K010462)**
- **Exergen TemporalScanner Thermometer(K011291)**

5.0 Device Description: **AViTA TS8/TS9 IR Ear/ Forehead Thermometer** is a hand-held, non-sterile, reusable, battery operated device that can measures human body temperature in 2 ways

(1) the temporal artery over forehead..
(2) Tympanic Temperature via the human ear.

Operation is based on the measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery or from the ear Tympanic .

6.0 Intended Use: The device is intended for the intermittent measurement and monitoring of human body temperature, by consumers in the home.

7.0 Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ASTM E1965-98, IEC 60601-1 and IEC 60601-1-2 requirements.

9. Conclusions:

The **AViTA TS8/TS9 IR Ear/ Forehead Thermometer** have the same intended use and similar technological characteristics as the **AViTA TS2(Piccolo)/TS4(Exato) Infrared Ear Thermometer (K010462)** Marketed By **AViTA Corp.** and **Exergen TemporalScanner Thermometer(K011291)** marketed by **Exergen Corporation.** Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **AViTA TS8/TS9 IR Ear/ Forehead Thermometer** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2003

AViTA Corporation
C/O Ms. Jennifer Reich
Harvest Consulting Corporation
3892 South America West Trail,
Flaggstaff, Arizona 86001, U.S.A.

Re: K031503
Trade/Device Name: AViTA TS8/TS9 Series IR Ear/ Forehead Thermometer
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 23, 2003
Received: September 29, 2003

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K031503

DEVICE NAME: AViTA TS8/TS9 IR Ear/ Forehead Thermometer
AViTA Corp.

INDICATIONS FOR USE:

The device is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

Silvana Cuevas

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031503

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-Counter V
(Per 21 CFR 801.109) (Optional Format)